PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Amalfitano *et al.*

Group Art Unit: 1633

Serial No.: 10/511,980

Examiner: Sajjadi, Fereydoun Ghotb

Filed: April 7, 2005

Docket No.: 180/151 PCT/US

Confirmation No.: 7130

For: VIRAL VECTORS AND METHODS FOR PRODUCING AND USING THE SAME

* *

DECLARATION OF ANDREA AMALFITANO, D.O., PH.D.
PURSUANT TO 37 C.F.R. §1.132

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. My name is Andrea Amalfitano, D.O., Ph.D., and I am the Osteopathic Heritage Foundation Endowed Professor of Pediatrics, Microbiology and Molecular Genetics at Michigan State University, and a co-inventor of the subject U.S. Patent Application Serial No. 10/511,980.

2. A true and accurate copy of my *curriculum vitae*, which evidences my expertise and credentials, is attached herewith and labeled **Exhibit B**.

3. I have had an opportunity to review pending claims 1-3, 5-7, 9, 17-23, 26-28, 30-33, 35, 36, and 145-147 in the above captioned U.S. Patent Application Serial No. 10/511,980.

4. I have also reviewed the following documents: the Non-Final Official Action dated August 4, 2009 on the above captioned U.S. Patent Application Serial No.

10/511,980 by the U.S. Patent and Trademark Office (USPTO), Lieber *et al.* (1999) 73 *J Virol* 9314-9324 (hereinafter "Lieber"), and U.S. Patent No. 6,383,794 to Mountz *et al.* (hereinafter "Mountz").

5. The presently claimed subject matter relates to recombinant hybrid viruses that when introduced into a packaging cell produce adeno-associated virus (AAV) particles that are essentially if not completely free of contaminating adenovirus. This is depicted in **Exhibit C**, and is believed to be in contrast to the disclosures of Lieber and Mountz, which disclose the production of Ad-AAV viruses encapsidated in adenovirus capsids or AAV vectors contaminated with adenovirus particles, respectively.

6. With respect to Lieber, **Exhibit D** is believed to depict a representative method disclosed in this reference. As can be seen in **Exhibit D**, Lieber is believed to disclose a method wherein 293 cells are infected with a vector. After 72 hours, the viruses that are produced are encapsidated in adenovirus capsids. This is set forth on page 9315, left column, first full paragraph of Lieber, which states in part: "Our hypotheses behind the generation of these hybrid vectors were· (i) that the AAV ITRs would mediate the formation of vector genomes devoid of all Ad genes that are packaged into Ad particles..." (emphasis added).

7. Turning now to Mountz, **Exhibit E** is believed to depict a representative method disclosed in this reference. As shown in **Exhibit E**, 293 cells are again infected with a vector, which would result in the production of some AAV vector but it is believed would also necessarily lead to a significant contamination with adenovirus particles. The resultant adenovirus contamination must then be removed by additional steps.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section

1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Andrea Amalfitano, D.O., Ph.D.

01.28.2010
Date

Attachments: **Exhibits B-E**

EXHIBIT B

MICHIGAN STATE UNIVERSITY
CURRICULUM VITAE

Date prepared: February 10

Andrea Amalfitano D.O., Ph.D.

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Primary academic appointments: Department of Pediatrics, College of Osteopathic Medicine; Microbiology and Molecular Genetics, College of Osteopathic Medicine
Secondary appointments: University Wide Program in Genetics, University Wide Program in Cell and Molecular Biology

Date of birth: 3/20/62 **Place:** Detroit, Michigan **Citizen of:** USA

Present academic rank and title: Osteopathic Heritage Foundation Professor of Microbiology and Molecular Genetics and Pediatrics
Date and rank of Michigan State University faculty appointment: 9/01/2005: Full Professor (Tenured)
Medical licensure: State of Michigan Perm. ID # 5101011076: Status: Active

Diplomate of the American Board Medical Genetics (DABMG)
-Maintenance of certification dates: Clinical Genetics: 9/96, Recertified 03/2006, 2009

Education:

Place:	Date:	Degree:
University:		
Michigan State University, Microbiology	1984	BS

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Graduate or Professional School:

Michigan State University		
College of Natural Sciences/Microbiology	1989	Ph.D
Michigan State University		
College of Osteopathic Medicine/Medical Degree	1990	D.O.

Scholarly societies:

American Society of Microbiology
American Society of Gene Therapy
Fellow, American College of Medical Genetics
Diplomate, American Board of Medical Genetics
American Osteopathic Association
Michigan Osteopathic Association

Post-Graduate Professional training and academic career:

1984-1990:	Medical Scientist Training Program, (D.O./Ph.D combined training program) Michigan State University, East Lansing, MI.
1990-1991:	Internal Medicine Internship, Michigan State University, Mt. Clemens General Hospital, Mt. Clemens, MI.
1991-1993:	Pediatric Residency, Dept. Of Pediatrics, The Mayo Clinic, Rochester, MN.
1993-1996:	Medical Genetics Clinical Fellowship, Dept. Of Pediatrics, University of Michigan Medical School, Ann Arbor, MI.
1996-2002:	Assistant Professor of Pediatrics, Division of Medical Genetics, Duke University Medical Center, Durham, N.C
1998-2005:	Assistant Professor of Molecular Genetics and Microbiology, Duke University Medical Center, Durham, NC.
2001-2005:	Acting Chief, Division of Medical Genetics, Duke University Medical Center, Durham, NC.
2002-2005	Associate Professor of Pediatrics, (with Tenure), Division of Medical Genetics, Duke University Medical Center, Durham, N.C.
2002-2005:	Assistant Professor of Pathology, Duke University Medical Center
2005-2006:	Associate Consulting Professor of Pediatrics, Duke University Medical Center, Durham, NC.
2005-present:	Osteopathic Heritage Foundation Professor (Tenured) of Microbiology and Molecular Genetics, Pediatrics, Michigan State University, East Lansing, MI.

EXHIBIT B

Publications:

Peer-Reviewed Journals:

1. S.Y. Oh, A. Amalfitano, K. Frederici, M.C. Chen, and M.M. Fluck. Low probability of double integration in transformation of nonpermissive cells by polyomavirus. J. of Virology, Vol. 62., p. 1304-1313, 1990.
2. J.A. Wirth, A. Amalfitano, R. Gross, M.B.A. Oldstone, and M.M. Fluck.Organ and age specific replication of polyomavirus in mice. J. of Virology. Vol. 66, p. 3278-3286, 1992.
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5. A. Amalfitano, C.A. Begy, and J.S. Chamberlain. Improved adenovirus packaging cell lines to support the growth of replication defective gene delivery vectors. Proc. Natl. Acad. Sci. Vol. 93 (8) pp. 3552-3556, 1996.
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9. Dubowitz syndrome: A defect in the cholesterol biosynthetic pathway?. A. Ahmad, A. Amalfitano, Y.T. Chen, and P. Kishnani. Amer. J. Med. Genetics (86) p.503-504. 1999.
10. H. Hu., D. Serra, and A. Amalfitano. Persistence of an [E1-, polymerase-] adenovirus vector despite transduction of a neoantigen into immune-competent mice. Human Gene Therapy 10 (3) p354-363, 1999.
11. A. Amalfitano, A. J. McVie-Wylie, H. Hu, T.L. Dawson, N. Raben, . Plotz, and Y.T. Chen. Systemic correction of the muscle disorder glycogen storage disease-Type II after hepatic targeting of a modified adenovirus vector encoding human acid-α-glucosidase. Proc. Natl. Acad. Sci (USA) Vol 96 (16) p8861-8866, 1999.
12. D. Hartigan-O'Connor, A. Amalfitano. and J.S. Chamberlain. Improved production of gutted adenovirus in cells expressing preterminal protein and DNA polymerase. J. Virology. 73 (9) p. 7835-7841,1999
13. A. Amalfitano. Next Generation Adenoviral Vectors: New and Improved. Gene Therapy, (6) 1643-1645, Oct. 1999.
14. Y.T. Chen and A. Amalfitano. Towards a molecular therapy for glycogen storage disease type-II (Pompe disease). *Molecular Medicine Today*, (6)245-251, 2000.
15. B.L. Hodges, D. Serra, H. Hu, C.R. Begy, J. S. Chamberlain, and A. Amalfitano. Multiply Deleted [E1-, polymerase-, pTP-] Adenovirus Vector persists despite deletion of the preterminal protein. *J.Gene Medicine* (2)250-259, 2000.

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Associated Virus 8 Pseudotyped (AAV2/8) Vector in Glycogen Storage Disease Type II (GSD-II).Molecular Therapy 2005 11(1):57-65.2005

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68. Michael A. Morse, Junping Wei, Zachary Hartman, Wenle Xia, Xiu-Rong Ren, Gangjun Lei[6], William Barry[7], Takuya Osada[8], Amy Hobeika[9], Sharon Peplinski[10], Haixiang Jiang, Gayathri R. Devi, Wei Chen, Neil Spector, Andrea Amalfitano, H. Kim Lyerly, & Timothy M. Clay. Synergism from combined immunologic and pharmacologic inhibition of HER2 in vivo. International Journal of Cancer. *In press.*
69. Sergey S. Seregin, Daniel M. Appledorn, Patial, S., Bujold, M, Nance, W., Godbehere, S., Narayanan Parameswaran, and Andrea Amalfitano. β-Arrestins modulate Adenovirus vector induced innate immune responses: differential regulation by β-arrestin-1 and β-arrestin-2. Virus Research. *In press.*
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Book Chapters:

EXHIBIT B

1. A. Amalfitano, J.A. Rafael, and J.S. Chamberlain. Structure and mutation of the dystrophin gene. Chapter 1 in: Dystrophin: Gene, protein, and cell biology.. Editors: S.C. Brown, J.A. Lucy 1997.
2. A. Amalfitano. In vivo gene targeting of neuronal cells. Chapter 13 in: Apoptosis in Neurobiology. CRC Methods in Neuroscience series. Editors: Hannun and Boustany, CRC Press, Boca Raton, Fl. 1998.
3. A. Amalfitano. Production of multiply deleted, helper virus independent Adenovirus vectors, Chapter 6 in: Viral vectors: Basic Science and Gene Therapy. Biotechniques Books. Editors A. Cid-Arregui and A Garcia-Carranca, 2000.
4. Z. Hartman and A. Amalfitano. Utility of Adenovirus-Based Vectors, Chapter 14 in : Handbook of Cancer Vaccines, Of the Series: Cancer Drug Discovery and Development. Editors: M. Morse, T. Clay, and H.K. Lyerly, Humana Press, Totowa, NJ. 2004.
5. A. Amalfitano. Utilization of Adenovirus vectors for multiple gene transfer applications., Chapter 13 in : Modern Mammalian Cell Transduction Techniques. Of the series "Methods" Editor: A. Peel. 2004. Academic Press, Editors: A. Peel. Methods. 2004 Jun;33(2):173-8.
6. Xu F., Serra D., and Amalfitano A. Applications of Adenoviral Vector-Mediated Gene Transfer in Cardiovascular Research. Methods Mol.Med 2006: 129:209-239.
7. Appledorn, D., Seregin, S., and Amalfitano, A. Adenovirus vectors for Renal Targeted Gene Therapy. *in* Contributions to Nephrology (159) :Gene Therapy for Renal Diseases and Transplantation. Eds: A. Benigni and G. Remuzzi.2008.

Selected abstracts:

1. J.S. Chamberlain, M.A. Hauser, J.A. Rafeal, K. Corrado, A. Amalfitano, R. Kumar-Singh. Targeted delivery and expression of dystrophin minigenes to muscle. The 77th Annual Meeting of the Endocrine Society, June 14-17, 1995, Washington, DC. Abstract Book, p.2.
2. J.S. Chamberlain, M.A. Hauser, J.A. Rafael, K. Corrado, A. Amalfitano, R. Kumar-Singh. Structure/function studies of dystrophin: Functional analysis of mini-dystrophin genes. Cell Bioc., 1995; 19C(S):362.
3. A. Amalfitano, C.A. Begy, M.A. Hauser, R. Kumar-Singh, and J.S. Chamberlain. Modification of adenoviral vectors for use in gene therapy of Duchenne muscular dystrophy. Presented at the 45th Annual meeting of the American Society for Human Genetics, *Symposium*- Gene therapy, how and when? Oct 26, 1995, Minneapolis, MN. Am J. Human Genetics 1995 57(4) Supplement. pA234.
4. J.S. Chamberlain and A. Amalfitano. Packaging cells expressing the Adenovirus (Ad) E1, polymerase, and preterminal proteins to allow the growth of a new class of replication defective Ad-vector for use in Duchenne muscular dystrophy (DMD). Am J. Human genetics 1996; 59(4) Supplement. pA377.
5. R. Kumar-Singh, D. Hartigan, M.A. Hauser, A. Amalfitano, and J.S. Chamberlain. Encapsidated adenovirus minichromosomes as gene-delivery vehicles. Presented at the 46th Annual meeting of the American Society for Human Genetics, Poster Session, Nov 1, 1996. Am J. Human Genetics 1996; 59(4) Supplement. pA202.
6. A. Amalfitano, and J.S. Chamberlain. The utilization of dystrophin-inducible mdx mice as a tool to assess the potential of gene therapy for Duchenne muscular dystrophy and

other muscle diseases. Presented at the 46th Annual meeting of the American Society for Human Genetics, Symposium: "Mouse models of human disease and development", Oct 31, 1996. Am J. Human Genetics 1996; 59(4) Supplement. pA195.

7. J.S. Chamberlain, M.A. Hauser, D. Calnek, C. Barjot, R. Kumar-Singh, and A. Amalfitano. Gutted adenoviral vectors for gene therapy of Duchenne muscular dystrophy. Keystone Symposia on the Molecular and Cellular Biology of Gene Therapy. Snowbird, Utah, April 1997.
8. A. Amalfitano, M.A. Hauser, and J.S. Chamberlain. A new class of adenovirus vector: the [E1-,E2b-]Ad vector. Keystone Symposia on the Molecular and Cellular Biology of Gene Therapy. Snowbird, Utah, April 1997.
9. A. Amalfitano, D. Serra, M.A. Hauser, J. S. Chamberlain, and H. Hu. In vivo effectiveness of improved adenovirus vectors. Molecular and Cellular Biology of Gene Therapy, Keystone CO. Jan 19-25, 1998.
10. J.Z. Baffi, A. Amalfitano, and KG Csaky. Evaluation of second generation adenoviral vectors for gene delivery into retinal pigment epithelial cells. Assoc. for Research in Vision and Ophthalmology, May, 1998
11. D. Hartigan-O'Connor, G. Salvatori, A. Amalfitano, and J.S. Chamberlain. Increased Efficiency of gutted adenovirus production in cells expressing preterminal protein and DNA polymerase. 1st annual meeting of the American Society of Gene Therapy, Seattle, WA. May 28-31, 1998.
12. A. Amalfitano, D. Serra, and H. Hu. Extended persistence and prolonged expression of highly immunogenic transgenes in immune-competnet animals via utilization of a unique class of adenovirus vector. 1st annual meeting of the American Society of Gene Therapy, Seattle, WA. May 28-31, 1998.
13. A. Amalfitano, D. Serra, MA Hauser, JS Chamberlain, and H. Hu. In vivo effectiveness of improved adenovirus vectors. Molecular and Cellular Biology of Gene Therapy, Keystone, CO., Jan. 1998.
14. Kishnani P, Ahmad A, **Amalfitano A**, Chen Y-T. Dubowitz syndrome: A defect in the cholesterol biosynthetic pathway? Poster Presentation at the 47th American Society of Human Genetics, Denver, CO. October 1998.
15. A. Amalfitano, H. Hu., A.J. McVie, T.L. Dawson, M. Pennybacker, N. Raben, P. H. Plotz, and Y.T Chen. A potential paradigm for the treatment of lysosomal disorders via modified adenovirus mediated gene therapy. American Society for Human Genetics, Oct 1998. Am J. of Human Genetics 1998: 63(4) Supplement p. A397.
16. A. Ahmad, M. Brinson, B. Hodges, J. Chamberlain, and A. Amalfitano. American Somatic down-regulation of dystrophin expression suggests that dystrophin is stable for extended periods in vivo. Society for Human Genetics, Oct 1998. Am J. of Human Genetics 1998: 63(4) Supplement p. A397.
17. Bradley Hodges, Huimin Hu, Delila Serra, and Andrea Amalfitano. 2nd Expanding the Scope of the "TWO-HIT" hypothesis: Influence of tissue type, host Strain, and Additional Vector Modifications upon the Extended persistence of [E1-,E2b-] Adenovirus vectors encoding foreign genes. Annual Meeting of the American Society of Gene Therapy, June 1999.
18. A. Amalfitano, H. Hu, A.J. McVie, T.L. Dawson, N. Raben, P. Plotz, and Y.T. Chen. The simultaneous correction of multiple muscle groups after a single intravenous

administration of a modified adenovirus vector. 2nd Annual Meeting of the American Society of Gene Therapy, June 1999.

19. B.L. Hodges, H. K. Evans, D. Serra, and A. Amalfitano. Efficient, High Level Production of Adenovirus vectors Deleted for Both E1 and 100K. 3rd Annual Meeting of the American Society of Gene Therapy, May 2000.
20. B.L.Hodges, D.Serra, and A.Amalfitano. [E1-,E2b-] Adenovirus Vectors Persistently Express Foreign Genes in the Skeletal Muscles of Non-tolerant Mice Without the use of Immune-suppression. 3rd Annual Meeting of the American Society of Gene Therapy, May 2000.
21. E. Ding, B.L. Hodges, A.J. McVie-Wylie, D. Serra, D. Koeberl, Y.T. Chen, and A. Amalfitano. Long Term Efficacy of [E1-,E2b-] Adenovirus Vector Mediated Gene Therapy for a Lysosomal Storage Disorder (Pompe disease) 3rd Annual Meeting of the American Society of Gene Therapy, May 2000.
22. AE Luebke, JD Stieger, BL Hodges, A Amalfitano. Cochlear Function During [E1-] and [E1-, E2b-] Adenovirus Transduction of Guinea Pig Hair Cells. University of Miami School of Medicine, Miami, FL 33136 and Duke University Medical Center, Durham, NC 27710. 3rd Annual Meeting of the American Society of Gene Therapy, May 2000.
23. A. Lubke, J. Steiger, B. Hodges, A. Amalfitano. A modified adenovirus can transfect coclear hair cells in vivo without compromising cochlear function. ARO Mid-Winter Meeting, Miami, FL, Feb 2001.
24. J.D. Harris, I.R. Graham, T. Athanasopoulos, S. Schepelmann, A.K. Stannard, B.L. Hodges, A. Amalfitano, D.G. Hassall, J.S. Owen, J.G. Dickson. Atheroprotective effects of Apolipoprotein E (ApoE) gene transfer to ApoE-deficient mice using recombinant adeno-associated virus and adenovirus (E1, E2b and E3 deleted) vectors. 4th Annual Meeting of the American Society of Gene Therapy, Seattle, WA, May 30-June 3, 2001
25. J.R. Holt, A. Amalfitano, A.E. Luebke. *In Vivo* and *In Vitro* Expression of Transgenes in Mammalian Vestibular Hair Cells Infected with [E1-], and [E1-, E2b-] Adenoviral Vectors. 4th Annual Meeting of the American Society of Gene Therapy, Seattle, WA, May 30-June 3, 2001.
26. A.E. Luebke, J.D. Steiger, R.J. Parks, A. Amalfitano. *In Vivo* Adenovirus-Directed Gene Transfer to the Inner Ear: 1st, 2nd, and 3rd Generation Adenoviral Vectors. Molecular Biology of Hearing and Deafness, Bethesda, MD, October 4-7, 2001.
27. Bulsara, K.R., M.B. Ficklin, M. Lu, A. Amalfitano and J.H.P. Skene. 2001. Adenovirus vectors for retrograde delivery and sustained expression of neuronal growth-associated genes after spinal cord injury. Soc.Neuroscience abstr. 257.18.
28. Kishnani P, Voit T, Nicolino M, Amalfitano A, Straub V, Klinge L, Tixier F, Braakman T, Cox GF, and Chen YT.The safety and efficacy of recombinant human acid alpha-glucosidase (rhGAA) in patients with classical infantile Pompe disease: Preliminary three month data from a Phase II study. Platform presentation, Annual American College of Medical Genetics meeting in New Orleans, LA, March 2002.
29. Kishnani P, Voit T, Nicolino M, Amalfitano A, Straub V, Klinge L, Tixier F, Braakman T, Cox GF, and Chen YT.The safety and efficacy of recombinant human acid alpha-glucosidase (rhGAA) in patients with classical infantile Pompe disease: Preliminary three month data from a Phase II study. Platform presentation at the Annual SIMD meeting in Pacific Grove, CA. March 2002.

EXHIBIT B

30. Sun BD, Amalfitano A, Chen Y-T, Bird A, Hou YX, and Koeberl DD. A modified hybrid adeno-associated virus-adenovirus vector encoding human acid-α-glucosidase (hGAA) for gene therapy in glycogen storage disease, type II (GSD II). 5th Annual Meeting, American Society of Gene Therapy, June 4-9, 2002, Boston, Massachusetts.
31. E. Ding, H. Hu, B. L. Hodges, F. Migone, D. M. Serra, F. Xu, Y. T. Chen, and A. Amalfitano. Efficacy of Gene Therapy for a Prototypical Lysosomal Storage Disease (GSD-II) is Critically Dependent Upon Vector Dose, Transgene Promoter, and the Tissues Targeted for Vector Transduction. 5th Annual ASGT meeting, Boston MA, June 2002.
32. HW Li, JZ Li, A. Amalfitano, GR Hankins, GA Helm. Construction of [E1-,E2b-] Adenoviral vectors with Human Bone Morphogenetic Protein -4 and -6 and Their Ability to Induce Ectopic Bone Formation in Rats.. 5th Annual ASGT meeting, Boston MA, June 2002.
33. Everett, R.E., Ding, E., Serra, D, and Amalfitano. Equivalent persistence of [E1$^-$, E2b$^-$] Ad vectors in diverse immunocompetent strains of mice accompanied by toxicity levels no different than those previously observed with use of "gutted" Ad vectors. 5th Annual ASGT meeting, Boston MA, June 2002.
34. Kishnani P, Amalfitano A, Bengur A, Morse R, Majure J, Case L, Veerling D, Mackey J, Smith W, McVie-Wylie A, Sullivan J, Hoganson G, Phillips J, Schafer G, Charrow J, Ware R, Bossen E, and Chen Y-T. Recombinant human acid α-glucosidase enzyme therapy for infantile glycogen storage disease type II: Results of a phase I/II clinical trial, American College of Medical Genetics Meeting, Miami, FL. Oral Presentation by March 2001.
35. Kishnani P, Voit T, Nicolino M, Amalfitano A, Straub V, Klinge L, Tixier F, Braakman T, Cox GF, and Chen, YT. Safety and efficacy of recombinant human acid alpha-glucosidase (rhGAA) in patients with classical infantile Pompe disease: Preliminary three month data from a Phase II study. Platform presentation at the Annual SIMD meeting in Pacific Grove, California. March 2002.
36. Kishnani P, Voit T, Nicolino M, Amalfitano A, Straub V, Klinge L, Tixier F, Braakman T, Cox GF, and Chen, YT. Safety and efficacy of recombinant human acid alpha-glucosidase (rhGAA) in patients with classical infantile Pompe disease: Preliminary three month data from a Phase II study. Platform presentation in Biochemical/Molecular Genetics at the Annual American College of Medical Genetics, Clinical Genetics meeting in New Orleans, LA. March 2002.
37. Levine J, Colan S, Kishnani P, Amalfitano A, Tsai CH, Herman G, Waterson J, Rogers RC, Yong F,Chen YT. Administration of Recombinant Human Acid Alpha Glucosidase (rhGAA) to Patients with Infantile Pompe Disease Results in a Rapid Decrease in Left Ventricular Hypertrophy (LVH): Preliminary Results from a Phase 2 Study. Am. Heart Assoc. 2002.
38. Kishnani, P; Voit, T; Nicolino, M; Amalfitano, A; Tsai, C H; Herman, G; Waterson, J; Rogers, A7; Landy, H ; Cox, G ; Braakman, T ; Corzo, D ; Thurberg, B ; Richards, S ; Chen, Y T 1 RECOMBINANT HUMAN ACID ALPHA GLUCOSIDASE (rhGAA) FOR TREATMENT OF CLASSICAL INFANTILE POMPE DISEASE (CIPD): PRELIMINARY DATA FROM A PHASE 2 STUDY. *Journal of Inherited Metabolic Disease. 25 Supplement 1:117, July 2002.*

EXHIBIT B

39. Robert J. Kaner, Franck Rahaghi, Dmitri Igonkin, Andrea Amalfitano, Robin B. Parks, Shawn Kuhmann, John P. Moore, Ronald G. Crystal. Ad E2b, in Part, Mediates Inhibition of HIV-1 Replication in Human Monocytic Cells. 6th Annual ASGT meeting, Washington, D.C. 2003.
40. Xu, F. Ding, E., Migone, F., Serra, D., Schneider, A, Chen Y.T., and Amalfitano, A. Development of a new, immune-deficient, GSD-II mouse model confirms that anti-GAA antibody can limit the efficacy of gene therapy for GSD-II. 6th Annual ASGT meeting, Washington D.C. 2003.
41. Xu, F. Ding, E., Migone, F., Serra, D., Schneider, A, Chen Y.T., and Amalfitano, A. Glycogen storage in multiple muscles of old GSD-II mice can be rapidly cleared after a single intra-venous injection with a modified adenoviral vector expressing hGAA. 6th Annual ASGT meeting, Washington D.C. 2003.
42. Eric Weaver, Zhongjing Lu, Yingying Li, Larry Liao, Benjiang Ma, Munir Alam, Richard Scearce, Laura Sutherland, Julie Decker, Zachary Hartman, Andrea Amalfitano, Bette Korber, Beatrice Hahn, David Montefiori, Barton Haynes, and Feng Gao. Immunogenicity of HIV-1 Group M Consensus Env Immunogens. AIDS Vaccine Meetings: New York, NY. Sep 18-21, 2003.
43. J D Harris, I R Graham, S Schepelmann, A K Stannard, A Amalfitano[3], D G Hassall, J S Owen, G Dickson. Protection against Atherosclerosis Utilising [E1, E2b and E3 deleted] Adenovirus Vectors containing Cellular and Liver-Specific Promoters Driving Expression of Human Apolipoprotein E (apoE) for Liver-Directed Gene Transfer in the apoE$^{-/-}$ Mouse. European Society of Gene Therapy , 11th Annual Congress, Edinburgh UK, Nov. 2003.
44. H. Jiang, R.Everett, Z. Wang, D.Serra, M.M. .Frank, A.Amalfitano. Recombinant Adenovirus vectors can bind the human complement protein C3 independent of anti-Ad antibodies, and subsequently activate the alternative complement pathway. Oral presentation: European Society of Gene Therapy , 11th Annual Congress, Edinburgh UK, Nov. 2003.
45. E.A. Weaver, Z. Lu, Y. Li, H-X. Liao, B. Ma, M.S. Alam, R.M. Scearce, L. Sutherland, J.M. Decker, Z. Hartman, A. Amalfitano, G. M. Shaw, B.T. Korber, B.H. Hahn, D.C. Montefiori, B.F. Haynes, F. Gao· Cross-subtype Immune Responses of HIV-1 Group M Consensus Env Immunogens. 11th Annual Conference on Retroviruses and Opportunistic Infections, San Francisco, CA, February 8-11, 2004.
46. Xiao Yi Yang, Takuya Osada, Bolyn Fralish, Christina Venturi, Donna Niedzwiecki, Michael A. Morse, Andrea Amalfitano, Jonathan Smith, H. Kim Lyerly, & Timothy M. Clay. A novel alphavirus vector expressing CEA breaks immunologic tolerance in mice transgenic for human CEA. AACR Annual meeting, Orlando, FL. Mar. 2004.
47. Takuya Osada, Xiao Yi Yang, Christina Bourgeois Venturi, Zachary Hartman, Delila Serra, Donna Niedzwiecki, Michael A. Morse, H. Kim Lyerly, Andrea Amalfitano, & Timothy M. Clay. A novel non-replicating adenoviral vector expressing carcinoembryonic antigen (CEA) breaks tolerance to CEA in CEA-transgenic mice. AACR Annual meeting, Orlando, FL. Mar. 2004.
48. Baodong Sun, Haoyue Zhang, Ayn Schneider, Andrew Bird, Andrea Amalfitano, Y.-T. Chen, and Dwight D. Koeberl. Correction of Glycogen Storage Disease Type II (GSD II) with an Adeno-Associated Virus 8 (AAV2/8) Vector. 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN .

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49. Luis Franco, Baodong Sun, Andrew Bird, Haoyue Zhang, Andrea Amalfitano, Y.-T. Chen, and Dwight D. Koeberl. Sustained, High-level Expression of Human Acid Alpha-Glucosidase and Correction of Glycogen Storage Disease Type II (GSD II) with an Adeno-Associated Virus 8 (AAV2/8) Vector Containing a Liver-specific Promoter. 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN.
50. Robert J. Kaner, Francisco Santiago, Dmitri Igonkin, Jerome Schaack, Andrea Amalfitano, Ronald G. Crystal. Ad DNA Polymerase and Preterminal Protein (pTP) Genes Each Mediate Inhibition of HIV-1 Replication in Human Alveolar Macrophages. 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN.
51. H. Jiang, R.Everett, A. Kiang, Z. Wang, H. Zhang, D.Serra, M.M. Frank, and A.Amalfitano. Ad interactions with the complement systems of humans and mice. 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN.
52. Shaoxi Liao, R. Everett, F. Xu, D. Serra, N. Van Rooijen, Andrea Amalfitano Improved Efficacy of Adenovirus-Mediated Gene Therapy For GSD-II Disease by Selective Depletion of Kupffer cells. . 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN.
53. A.Kiang, F.Xu, S. Liao, D. Serra, D.J.Palmer, P. Ng, A Amalfitano. Unique potential of gene therapy for GSD-II using fully deleted adenovirus based vectors expressing hGAA. 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN.
54. A. Kiang[1], Z. Hartman[1], J. Wei[1], D. Serra[1], H. Jiang[2], M.M. Frank[2], A. Amalfitano[1]. Evasion of the Innate Immune Response in Adenovirus Infused Complement C3 Deficient Mice. 8th Annual Meeting, American Association of Gene Therapy, 2005, St. Louis, MO. A. Kiang: Winner, Young Investigator Award.
55. Z. Hartman, A. Kiang, R. Everett, E. Black, J. Nevins and A. Amalfitano. *Novel in vitro* and *in vivo* transcriptome analysis identifies new Adenovirus responsive, innate gene networks. 8th Annual Meeting, American Association of Gene Therapy, 2005, St. Louis, MO.
56. Xu, F, Serra, D, A.Amalfitano. A novel replication competent, but packaging deficient adenoviral (Ad) vector [E1+, 100K-] for high level hGAA expression and reduced toxicity in gene therapy of Glycogen Storage Disease II (GSD-II). 8th Annual Meeting, American Association of Gene Therapy, 2005, St. Louis, MO. F. Xu: Winner, travel award.
57. In vivo, High Throughput analysis expands the known anti-Ad innate immune response profile, and implicates TLR pathways in Ad cellular immune response. 9th Annual Meeting, American Society of Gene Therapy, 2006, Baltimore, MD.
58. A new, plasmid-based adenoviral vectoring system derived from the highly immunogenic, human Ad4 strain. Hartman Z.C., Mendelson T., and Amalfitano, A.9th Annual Meeting, American Society of Gene Therapy, 2006, Baltimore, MD.
59. Decreased DHA in diabetic retina is caused by reduction in retinal specific elongase, Elovl-4. Maria Tikhonenko, Sergey Seregin, Andrea Amalfitano and Julia Busik. American Diabetes Association: 67th Annual Scientific Sessions; June 22-26, 2007.

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60. Identification of TLR2 as a mediator of the innate immune response to adenoviral vectors.Appledorn, DM; Scott, JS; Amalfitano 10th Annual Meeting of the American Association of Gene Therapy.2007
61. TLR4 and TRIF play both positive and negative roles in Ad induced innate immunity *in vivo*. Appledorn, DM; Hartman, ZC; Scott, JS; Amalfitano, A.10th Annual Meeting of the American Association of Gene Therapy.2007.
62. Characterization of Adenovirus Serotypes Representative of Groups A-E. Appledorn, DM; Scott, JS; Kiang, A.; Amalfitano, A 10th Annual Meeting of the American Association of Gene Therapy.2007. (Selected for oral Presentation.).
63. Adenovirus Induced Innate Immune Responses are Mediated in Part by the Presence of Natural Antibodies in Ad naive Mice. Jeannine M. Scott, PhD[1], Tyler T. Voss, BS[1], Daniel M. Appledorn, PhD[1] and Andrea Amalfitano, DO, PhD[1,2]. 10th Annual Meeting of the American Association of Gene Therapy.2007.
64. Adenovirus vector induced immune responses are dependent upon muti-faceted interactions with proteins of both the alternative and classical complement pathways in vivo. Scott, JS., Kiang,A., Appledorn, D, McBride, A.,Amalfitano, A. 10th Annual Meeting of the American Association of Gene Therapy.2007. (Selected for oral presentation).
65. *Campylobacter jejuni*-induced Activation of Murine Dendritic Cells Involves Cooperative Signaling through MyD88 and TRIF. Vijay A.K. Rathinam, Daniel M. Appledorn, Jennifer D. Olmstead, Kathleen A. Hoag, Andrea Amalfitano and Linda S. Mansfield. Annual American Society of Microbiology Meeting Boston, MA. 2008
66. Transient pre-treatment with glucocorticoid ablates innate toxicity of systemically delivered adenoviral vectors without reducing efficacy. ASGT 12-th annual Meeting, May 27 – May 30, 2009, San Diego, CA, USA: 639
67. Complement receptors regulate several aspects of Adenovirus (Ad) vector induced innate and adaptive immune responses *in vivo*. ASGT 12-th annual Meeting, May 27 – May 30, 2009, San Diego, CA, USA. 957.
68. Improved safety profile of novel Adenovirus based vectors "capsid-displaying" complement inhibitors: increased potential for cardiovascular gene transfer applications. American Heart Association Scientific Sessions, November 14 – 18, 2009, Orlando, FL, USA (selected for Oral Presentation).

Editorial Activities:

Editorial Board:
Molecular Therapy: *The Journal of the American Society of Gene and CellTherapy* ,
Gene Therapy
Editorial Advisory Board: Current Gene Therapy
Invited outside expert/reviewer: Selected Journals include:
American Journal of Medical Genetics
Bio-techniques
Biochimica et Biophysica Acta: Molecular Basis of Disease
Biotechnology Progress

EXHIBIT B

Expert Opinion on Biological Therapy
Expert Review of Vaccines
Gene Tests
Gene Therapy
Human Gene Therapy
Human Molecular Genetics
International Journal Of Cancer
In Vitro Cellular & Developmental Biology
Journal of Clinical Investigation
Journal of Cellular Physiology
Journal of Gene Medicine
Journal of Immunology
Journal of Pharmacology and Experimental Therapeutics
Journal of Virological Methods
Journal of Virology
Lancet
Molecular Genetics and Metabolism
Molecular Medicine
Muscle and Nerve
Transgenic Research
Trends in Biotechnology
Vaccine

Scientific Advisory and/or Consultant appointments (Selected):

-Founding Member, State of Michigan Newborn Screening Metabolic Disorders Quality Improvement Committee. 2009-Present
-Invited Member, National Gene Vector Bio-repository (NGVB) External Advisory Board: 2008-Present.
-Invited reviewer: National Institutes of Health/NIDDK ZDK1 GRB-S (01): Special Emphasis Panel, invited expert reviewer of Molecular Therapy Core Center grant applicants. July 2008.
-Invited Member, Grants Advisory Panel, Blue Cross and Blue Shield of Michigan Foundation, 2008-Present
-Invited Consultant: Gerson Lehrman Group; Council Member: 2007 -present
-Invited Expert-World Technology Evaluation Center (WTEC) Workshop on North American Research and Development in Rapid Vaccine Manufacturing, "Concepts Regarding Adenovirus based Vaccine Systems": 2007.
-American Society of Gene Therapy- Appointed Member, Committee on Gene Therapy for Genetic/Metabolic Diseases, 2006-Present
-Governor Appointed Member, State of Michigan Newborn Screening Advisory Panel, Appointed as Michigan Osteopathic Association Representative: 2006- present.
-Invited Scientific Advisory Board: Etubics Corporation, Seattle, WA. 2006-present

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-American Board of Medical Examiners, participant in ABME Clinical Genetics Certifying Examination Standard Setting Criteria Review Committee 10/2005.
-National Institutes of Health, Ad Hoc Member, HIV/AIDS Vaccines Study Section (VACC) Vaccine Therapeutics Study Section, 2004,2005
-Data Safety Monitoring Board Member, Ark Therapeutics, Ltd, Trinam™ study 2003-2007.
-American Society of Gene Therapy Annual Meeting, Faculty:1998, 2000, 2002, 2003, 2004,2006,2008,2009
-Annual Meeting of the American Society of Gene Therapy Moderator, 2003,2004,2006.
-Consultant, Etubics Corporation, Seattle, WA . 2006-Present
-National Institutes of Health, Member GTIE (Gene Therapy and Inborn Errors of Metabolism) Study Section *ad hoc* Panel Member, 2003-present
-National Institutes of Health, Medical Biochemistry (MED-B) Study section panel member 1999-2003.
-National Institutes of Health, Heart, Lung, and Blood Program Project Special Emphasis Review Committee, Gene Therapy Center of Excellence Grant Review. 2001
-Glycogen Storage Disease Association, *Ad hoc* Scientific Reviewer, 2000-present
-National Institutes of Health, Small Business Initiative Study Section Invited Reviewer, 2000.
-Muscular Dystrophy Association, *Ad hoc* Scientific Reviewer: 1999-present
-Genzyme Corporation, Pompe and Lysosomal Disease Scientific Advisor, Consultant, 1998-present.
-National Institutes of Health, National Institute on Aging, Biological Aging Review Committee,(NIA-B) Study Section, Invited reviewer, 1998
-National Instititutes of Health, Special Emphasis Panel/Scientific Review Group 2006/10 SBSR meeting, Skeletal Biology Structure and Regeneration Study Section

Patents/Inventions/

-"Adenovirus Vectors"-United States Patent. #6,063,622: Issue date:5/16/2000.
-"Deleted Adenovirus vectors and Methods of Making and Administering the Same". United States Patent: #6,328,958 Issue date: 12/11/2001.
-"Helper Adenovirus Vectors" US Patent #6,451,596: Issue Date: Sep. 17, 2002
-"Deleted Adenovirus vectors and Methods of Making and Administering the Same". United States Patent: #6,797,265: Issue date 9/28/2004.
-"Replicating Adenovirus Vectors" US Patent #6,946,126: Issue date: Sep. 20, 2005.
-"Methods of screening for risk of proliferative disease and methods for the treatment of proliferative disease" US Patent #7,129,043: Issue Date Oct 31, 2006.

-Numerous Patents awarded or pending via overseas PTO in reference to above US patents.

Corporations derived from Patents/Inventions:

-Etubics Corporation:a Biotechnology Corporation focused on advanced gene transfer technologies for vaccine development. See Etubics.com. Dr. Amalfitano is a consultant, scientific advisor, as well share holder in Etubics Inc.

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Professional awards, invited speaker, and other special recognitions:

-Invited Key-Note Speaker, St Vincent Mercy Medical Center Annual Research Day. "Translational Research" .May 13, 2009.

Invited Speaker: "Adenovirus Vector based Gene Transfer: Benefits and Limitations". Department of Medical and Molecular Genetics, Indiana University/Purdue University-Indianapolis Medical Center. Aug 27, 2008.

-Organizer : Mini-symposium on Gene Transfer. Current Clinical and Pre-clinical advancements. Symposium featuring top investigators in the field of clinical gene transfer, held at Michigan State University. 2008.

-Invited Speaker: Gordon Research Conference on the Science of Viral Vectors for Gene Therapy: The Host Response to Viral Infection. Adaptive Immune Responses to Viral Infection: "Adenovirus interactions with the Innate and Adaptive Arms of the Immune System. March 2-7, 2008.

-Invited Speaker: Pompe Disease: Pathogenesis, Genetics, and Treatment Strategies, Grand Rounds, Dept. of Neurology, University of Toledo Health Sciences Center, 2008

-Invited, Symposium Moderator: American Society of Gene Therapy, Session on Gene Therapy and Inherited Disease (declined due to scheduling conflict).2008

- Invited Speaker: WTEC Study on Vaccine Manufacturing: Workshop on Science and Technology in North American Rapid Vaccine Manufacturing: Concepts Regarding Adenovirus Based Vaccine Systems". Arlington VA.2007.

-Invited, Symposium Moderator: American Society of Gene Therapy, Session on Innate Immune Responses to Viral Vectors, 2007.

-Invited Speaker- Current Advances in therapy of Pompe Disease, MDA musculoskeletal clinics in San Francisco, Chicago, and Detroit, 2006-2007

-Invited Speaker and Participant , Symposium Workshop on "Muscle Glycogenoses", October 2007, Genoa-Quarto, Italy, 2006

-Osteopathic Heritage Foundation Endowed Professor, Michigan State University, 2005.

-Invited Speaker –Pediatric Academic Societies 2005 Annual Meetings, Washington, DC. May, 2005.Virus-Host Interactions: Mechanisms Underlying Persistent viral infections: PAS/PIS Topic Symposium Adenovirus Based Vectors as Tools to Understand Viral Persistence "Applying Viral Immune evasion strategies to adenovirus gene therapy vectors".

EXHIBIT B

-Invited Speaker AGSD (UK) Patient Conference and International Pompe Association Meeting Birmingham, United Kingdom, Oct 9-10, 2004.

-Invited Speaker, University Of Alabama-Birmingham, Gene Therapy Institute, Lecture Series on Gene Therapy Initiatives/Research: "Adenovirus gene transfer, Potential and Limitations" Sep 28,2004.

-Invited Speaker: Adenovirus interactions with the complement systems of humans and mice. H. Jiang, R.Everett, A. Kiang, Z. Wang, H. Zhang, D.Serra, M.M. Frank, and A.Amalfitano. 7th Annual Meeting, American Association of Gene Therapy, June 2-5, 2004, Minneapolis, MN.

Invited Speaker: Acid-Maltase Disease Association Teleconference for Patients: "Gene Therapy and Pompe Disease" Mar 23, 2004.

Invited Speaker: Mid-winter meeting of the Association for Research in Otolaryngology, Feb 2004. "Virally Mediated Gene Transfer, from Virology to Practice-Modified Adenovirus vectors offer multiple advantages for gene transfer research". Daytona, Florida.2004

Invited Speaker: 11th Annual meeting of the European Society of Gene Therapy, Nov 2003. "Complement and Adenovirus vectors". Edinburgh, Scotland

Invited Speaker: 2nd annual meeting of the International Pompe Association: Oct 2003: Heidelberg, Germany "Gene Therapy for Pompe Disease".

Invited Speaker: Cardiovascular Gene Transfer Symposium. 5th Annual Meeting of the American Society of Gene Therapy 2002, Washington, D.C.

-Invited Speaker: Educational Symposium on Adenovirus Vectors. Multiply-Deleted Ad Vectors, Clinical Trials and Immunological Responses to Vector Delivery. 5th Annual Meeting of the American Society of Gene Therapy 2002, Washington, D.C.

-Invited Speaker: The 2nd International Symposium on DNA Vaccine and Gene Therapy Technology. "Optimization of Adenovirus based vectors for multiple gene transfer approaches"; December 12-14, 2002. Taipei, Taiwan.

-Invited Speaker: North Carolina Pediatric Society Annual Meeting, Sep 2002, "Gene therapy: Where have we been and where are we going?

-Awardee: NIH/NICHD Pediatric Research Loan Repayment Program, with annual competitive renewals awarded :Sep 2002-2006.

-Invited Speaker: Plenary Session, 5th Annual Meeting of the American Society of Gene Therapy, June 2002

EXHIBIT B

-Invited Plenary Session (Advances in Pre-clinical Research) Speaker at 2002 HIV Vaccine Trials Network Full Group Meeting, "Adenovirus biology and why are they good vectors": Alexandria, VA:May 2002.

-Invited Speaker: 2001 Think Tank Symposium on Gene Therapy for Eye Diseases: "Benefits and Limitation of Adenovirus based gene transfer for ocular disorders" Sponsored by the Glaucoma Foundation. New York, New York, USA.

-Co-led "first-in-man" Phase I/II Clinical Trial of Myozyme enzyme infusion therapy for infantile Pompe Disease. Duke University Medical Center, Durham, NC. *Myozyme subsequently approved for human use by FDA in April 2006 as a direct result of this and othersubseqent clinical trials.*

-Invited Speaker: National Taiwan University Hospital: Applications of Gene Therapy to Human Diseases. 2001.

-Invited Speaker: Taiwan Center for Drug Evaluation, (Taiwan FDA equivalent). "Understanding Adenovirus based vectors and their potential for safe, clinical use". 2001.

-2001 Michigan State University College of Osteopathic Medicine Alumni of the Year Award.

-Invited Speaker: Plenary Session, 4th Annual Meeting of the American Society of Gene Therapy, June 2001

-Invited Speaker, University of North Carolina at Chapel Hill, Dept of Gene Therapy, "Utilization of Adenovirus based Vectors. 2000.

-"Adenovirus vector gutted" **Nature Biotechnology** "Research News Briefs" highlighting findings published by Amalfitano Lab. Nature Biotechnology: Vol 17 pp: 317: 1999,

-Invited Speaker: Scientific Symposium on Nonintegrating viral Vectors. "Improvements in the Biology of Modified Adenovirus vectors. 2nd Annual Meeting of the American Society of Gene Therapy 1999.

-Invited Speaker, Stanford University Dept. of Medical Genetics. Gene Therapy approaches to Genetic Disease.1999

-Invited Speaker, Berlex Industries: Modification of Adenovirus based vectors for improved efficacy in multiple human diseases.1998.

-Invited Speaker, Brown University Pediatric Grand Rounds: Genetics Update.1998

-Invited Speaker, Michigan State University, Genetics Primer for Primary Care Physicians-1998

EXHIBIT B

-NIH James B. Shannon Award for Promising Young Investigators: (NIH) Sept 1997-1999, "Modified Adenovirus Vectors for Gene Therapy" $50,000/yr.

-Howard Hughes Young Investigator Award-1996

-Diplomate, American Board of Medical Genetics, Clinical Geneticist, 1996, Recert. 2006

Certifications/Licensures:
Board Certified, Medical Genetics-Clinical, Sep. 1996., Recertified 2006
State of North Carolina Medical License, status: inactive.
State of Michigan Medical License, 1990-1996, 2005-Currently Active
State of Minnesota Medical License 1991-1993.status inactive

Organization Memberships:
American Society of Human Genetics
American College of Medical Genetics (Fellow)
American Society for Microbiology
American Society of Gene Therapy
American Osteopathic Association

EXHIBIT B

Areas of research interests:

-Basic Research into several aspects of Gene therapy, virus-mediated, non-virus mediated.
-Research into basic physiology of Duchenne Muscular Dystrophy/Glycogen storage disease Type II/Pompe disease/musculoskeletal disorders.
-Clinical enzyme replacement trials in Infantile GSD-II/Pompe disease
-Applied Gene therapy in several human diseases.
-Use of gene transfer to treat cancers, to augment anti-cancer immunity.
-Genetic Vaccine development for use in infectious diseases.
-Use of animal models of human disease to predict clinical outcomes of potential therapies.
-Understanding innate and adaptive immune responses to gene transfer
-Clinical Dysmorphology and syndrome classification/identification
-Pre-emptive clinical strategies for patients affected by any variety of genetic diseases.

External support–:

-RO1-NIH: DK069884-04-A1: Adenovirus Vectors and Complement System, (PI: A. Amalfitano)-03/05-2/08. (175,000/yr). Status: **In Renewal Phase.**

-DOD:/USA Med Res. Acq Activity 9/15/06-9/14/011
PI: T. Clay (Duke Univ.)
Sub-PI A. Amalfitano 10% Effort
Rapid Translation of a Novel and Potent Vaccine in HER2+ Metastatic Breast Cancer Patients"
Adenovirus vectors capable of expressing the her2/neu antigen will be produced. These vectors will then be delivered to Dr. Clay for downstream testing in cell and animal models. Status: **Active**

-PO1-NCI/NIH: 2PO1-CA078673-05A2 : Immunotherapy with High Frequency CEA Specific T cells, (PI : K. Lyerly)-
Project #3: Recombinant Adenovirus Based Vectors, (PI. A.Amalfitano (8/04-7/09)). (~$200,000/yr). Status:**Active**

-AHA Fellowship grant: ID #0815660G: Adenovirus vectors for Cardiovascular Research: Mentor for Award to Sergey S. Seregin. 2008-2010

-RO1-NIH: DK069884-04: Adenovirus Vectors and Complement System, (PI: A. Amalfitano)-03/05-2/08. (175,000/yr). Status: **Complete.**

-Genzyme Pharmaceutical Ltd. Program Project Sponsored Research Agreement. Gene Therapy of Pompe Disease: (PI: YT Chen, P.I.#3: A. Amalfitano: (10/01/99-12/30/06) Adenovirus mediated gene therapy of glycogen storage disease type II. ($~160,000/yr). Status: **Completed**

-Children's Miracle Network Award, (P.I.:A. Amalfitano) 2/05/-2/06 "Innate Cellular Responses to Adenoviral Gene Transfer". Status:Completed

-NIH/RO1 CA089573-01: 2/1/01-01/31/2006 (PI: HK Lyerly) 5% effort: A. Amalfitano

EXHIBIT B

$246,571/Yr. Dendritic Cell Mobilization and Active Immunotherapy. **Status: Completed**

-NIH/PAR-01-110: 7/1/03-6/30/08 (PI: HK Lyerly) 7% effort : A. Amalfitano.Annual Direct Costs : $1,664,273. "Specialized Program of Research Excellence in Human Cancer. **Status: Completed.**

-Genzyme Pharmaceutical Ltd. Sponsored Research Agreement (co PI: P. Kishnani / A. Amalfitano, 5/01/98- Ongoing) Research on enzyme replacement therapy for Pompe disease. Status: **Completed**, non-supported effort.

-Muscular Dystrophy Association (USA): 9/01/01-8/31-04 (PI: A. Amalfitano) "Therapeutic potential of replication competent or incompetent Adenovirus vectors encoding human acid-α-glucosidase in animal models of glycogen storage disease-type II.". ($105,000/yr) **Status:Completed.**

-NIH/RO1 HL65360-01: 08/01/00-07/31/04 (PI:WJ Koch) 5% effort: A.Amalfitano $250,000/Yr Targeting G proteins in Vascular Intimal Hyperplasia. **Status: Completed**

-NIH/RO1 HL56025-04: 1/01/01-12/31/04 (PI: WJ Koch) 5% effort: A.Amalfitano $175,000/Yr β-Adrenergic Gene Transfer and Myocardial Function. **Status: Complete**

-NIH/RO1 HL59333-04:1/01/01-12/31/04(PI:WJ Koch) 5% effort: A. Amalfitano $145,955/Yr Gene Transfer to Alter Transplanted Heart Function. **Status: Completed**

-NIH/RO1: DC 08036: 9/01/01-8/31/04 (PI. A. Luebke) "Molecular Biology of Cochlear Efferent Receptors" Sub-contract: A. Amalfitano (3% effort) $5,000/year Status: **Completed**

-Florida Biomedical research program: 6/01/01-7/31/02 (PI: A. Luebke) :Gene Transfer of the acetylcholine receptor to correct tobacco related hearing loss (Service Contract: PI: A. Amalfitano). Status: **COMPLETED.**

NIH/R01 NIDDK 52925-04, (PI: A. Amalfitano, June 1998-2002) "Modified Adenovirus Vectors for Gene Therapy"- $216,000/yr #1. Total Direct and Indirect costs. **Status: Complete**

-James Shannon Award for Young/New Investigators: (NIH) Sept 1997-1999, "Modified Adenovirus Vectors for Gene Therapy" $50,000/yr. **Status: COMPLETED**

-Childrens Miracle Network Grant (1997) "Establishment of a new animal model for the study of muscle diseases" $15,000/yr. **Status: COMPLETED**

-March of Dimes Research Award (June 1998-2000) Modified Adenvoirus vectors for gene therapy, $50,000/yr **(Declined secondary to simultaneous NIH/NIDDK-RO1 award).**

-Muscular Dystrophy Association (USA) (January 1998-2001) " A new animal model for the study of Duchenne Muscular Dystrophy" $80,000/year . **Status: COMPLETED**

EXHIBIT B

Clinical Activities

Michigan State University: 2005-present
Professor, College of Osteopathic Medicine, Department of Pediatrics
Training of Fellows, Residents, and Medical Students. Specialization in dysmorphology, development delay assessment, and metabolic inborn errors of metabolism.

Okemos Pediatrics Associate, Genetics Clinic: Inpatient and Outpatient Medical Genetic evaluation of patients and their families:

Staff Physician: Sparrow Hospital, Lansing, MI
Ingham Medical Center, Lansing, MI

Duke University –

2001-2005 Acting Chief, Division of Medical Genetics and Metabolism, Dept. of Pediatrics, DUMC.Clinical Medical Genetics Staff Physician, Full Hospital Privileges, Consultant for Inpatient Metabolic and Genetics Service.

Clinical Research: Co-PI: Enzyme replacement therapy in infants with GSD-II, ongoing clinical trial.

Current and Past Participation in academic and administrative activities:

Michigan State University: 2005-Present

-MSU-COM Medical School Admissions Committee, 2009-Present.
-Member, MSU-MMG Honors and Awards Committee, 2009-Present
-MSU Foundation, SPG Grant Review Committee, 2009
-Faculty Member, Center for Integrative Toxicology, 2008-Present
-Dept of Microbiology and Molecular Genetics Graduate Program, 2005-Present
-Faculty, MSU Graduate Program in Genetics.2005-Present
-Member, MSU-COM Patenge Endowed Chair Faculty Search Committtee, 2006-Present
-Faculty, MSU Cell and Molecular Biology Graduate Program, 2005-Present
-Member: College of Osteopathic Medicine Research and Graduate Study Committee.2006-Present
-Member, MSU Cell and Molecular Biology Executive Advisory Committee; 2007-2009.
-Member, MSU-COM DO/PhD program External Review Committee : 2007
-Chairman: College of Osteopathic Medicine Research and Graduate Study Committee.2006-2009
-Member, MSU Genetics Faculty Search Committee, 2006-2008
-Member, MSU Immunology Faculty Search Committee 2006-2007
-Member, MSU-MMG Faculty Advancement and Tenure Committee 2006-2008

EXHIBIT B

Duke University and Medical Center: 1996-2006

-Acting Chief, Division of Medical Genetics, Dept. of Pediatrics, Duke University Medical Center, 2001-2005
-Co-Chairman, Duke University Institutional Bio-safety Committee-2004-2005
-Duke University Institutional Review Board (IRB) for Clinical Research., Primary Member for Dept. of Pediatrics. 1999-2005
-Duke University Institutional Animal Care and Use Committee and Subcommittees, Primary Member for Dept. of Pediatrics: 1996-2004.
-Duke University Institutional Bio-safety Committee Ad hoc member:2003-2005
-Duke University Institute of Genome Sciences and Policy, Center for Genomic Medicine Director Search Committee member, 2004-2005.
-Genetics Mentor for Pediatric Residents-2003-2005
-Childrens Miracle Network, Duke University Medical Center, Reviewer, 1998-2005
-Duke University Faculty Search Committee: Division Chief Pediatric Neurology, 1997-1998
-Duke University Committee on Clinical Quality Improvement, 1997-1999
-Duke University Medical Center, Medical School applicant interviewer. 2003-2005
-Duke University Dept. of Pediatrics Residency Program, Applicant Interviewer 1998-2005
-Duke University Program in Genetics, Applicant Interviewer 2000-2005
-Duke University Dept.Molecular Genetics and Microbiology, Applicant Interviewer 1999-2005
-Duke University Dept. of Cellular and Molecular Biology Applicant Interviewer, 2004-2005
-Duke University MSTP applicant interviewer, 2000-2005
-Duke University Dept. of Pediatrics Faculty Development in Research, Sub-Committee: 1999
-Duke University Faculty Search Committee: Cytogenetics Head, Dept of Pathology, 1999.
-Participating Mentor: 3rd year Medical Students Research Experience in Human Genetics:1997- 2005
-Participating Mentor: Dept of Pediatrics Neonatal Research Training Program, 1999-2005

Research Laboratory Mentor:

Michigan State University Mentoring and Teaching: 2005-Present

MSU Ph.D, Post-doctoral Trainees:	Start	End
Jeannine Scott Ph.D.	October 2005	July 2007
Daniel Appledorn Ph.D	June 2006	Current

EXHIBIT B

MSU Graduate Students-

Name	Program	Date Start	Date End
Aaron J. McBride	CMB	Feb 2006	Current
Sergey Seregin	MMG	Sep. 2006	Current
-Awardee American Heart Association Fellowship 2008-2010			
Tyler Voss	DO/PhD/CMB	Feb 2007	Current
Nathaniel Schuldt	Genetics	Oct 2007	Current
Youssef Koussa	DO/PhD/BMB	Aug 2007	Current
Yasser Aldhamen	Genetics	Nov 2007	Current
Joyce Li	DO/PhD/Genetics	Nov 2007	Current
Dionisia Quiroga	DO/PhD/CMB	Oct 2007	Current

MSU Under-Graduate Students Mentoring:

Megan Hoban: PA, Winner 2007 MSU Gloss Award for promising undergraduate research.
Viktoria Iakounina: Winner 2007 Sayer Award for Outstanding undergraduate in Microbiology and Molecular Genetics, currently attending Medical School:ECU

William DePas: Winner 2008 MSU Gerhardt Award for promising undergraduate research. Currently at U of Michigan PhD program in Immunology.
Brandi Burke
William Nance
Ryan Stringer: MSU-SOMA , Currently in College of Osteopathic Medicine, MSU, Currently MSU-COM medical Student.
Kevin Raehtze: PA,
Jennifer Zehnder
Johnathon M. David

International Visiting Scholars-Mentoring

Seregin, Sergey	Feb 2006	Sep 2006

MSU Graduate Student Ph.D Committee Member:	Program	Completed
Sebla Kutluay	CMB	2009
Eric Marrotte	CMB	2009
Irina Theodora Szasz	MMG	
Li Li	MMG	
Mo Chen	MMG	2008
Wei Zou	MMG/EIT	
Bahareh Behrouz	Neurosci.	2008
Eleni Beli	FoodTox/(MS)	2008
Sonika Patial	CMB	

EXHIBIT B

Christine Dugan	DO/PhD/CMB	
Eric Schauberg	DO/PhD/CMB	
Laura Harris	CMB/MS	2008
Raba Abbas Al-Tamimi	Genetics	
Madalina Opreanu	MMG	
Wei Min	MMG/EIT	

Formal Course Lectures:

Course	College	Title
BMB 526 **Course Leader**	**COM** **CHM**	**Medical Genetics**
MMG 892 **GEN 800** **CMB 800** **VM 820** **Course Leader**	**COM, CHM, CVM**	**Gene Transfer Seminar**
OST 528	**COM**	**Growth and Development**
MMG 813	**CNS, COM**	**Advanced Virology**
PSL 950	**CHM**	**Seminar: Inflammation**
MMG 300	**College of Natural Science**	**Introduction to Genetics**
MMG 101	**College of Nat. Sci/MMG**	**Introduction to Microbiology**

Duke University Mentoring and Teaching: 1996-2006

M.D., Medical Genetics Fellows:	Approximate Start	Approximate end
Ayesha Ahmad	August 1997	June 1999

-Dr. Ahmad was awarded top honors, and the Dept. of Pediatrics First Annual Fellows Research award, based on research from her lab experiences, June, 1999.
-Currently Staff Physician, Wayne State University Dept. of Genetics.

EXHIBIT B

Deitrich Matern M.D. Dec 1998 Oct 1999
-currently Clinical/Research Staff Physician, The Mayo Clinic , Rochestor MN.

Ph.D, Post-doctoral Trainees: Approximate Start Approximate end

-Huimin Hu Ph.D. April 1997 April 1999
-currently a Research Associate, St. Judes Research Center Nashville, TN

-Bradley Hodges Ph.D June 1998 Sept. 2000
-awarded Childrens Miracle Network Grant June 1999
-currently a Research Associate, Genzyme Corp. Framingham, MA

-Enyu Ding Ph.D. Sept. 1999 Sept 2002
-Research Specialist, Comprehensive Cancer Center, Duke University Medical Center, Durham, NC.

-Ruth Everett, Ph.D. Jan. 2001 Feb 2004
-awarded Childrens Miracle Network Grant June 1999
-currently Research Associate, University of North Carolina at Chapel Hill, Chapel Hill, NC.

-Shaoxi Liao Ph.D April 2003 May 2004
-currently Research Associate, Duke University Medical Center, Durham,NC

-Junping Wei M.D. October 2004 2005
-currently Research Associate, Duke University Medical Center, Durham, NC.

Post-Graduate Students Approximate Start Approx end

Medical Students-3rd year

Paula Peake Sep 1998 Sep 1999

Duke Graduate Students-1st year rotations

Name	Program	Date Start	Date End
Heather Evans	UPG	Feb 1999	June 1999
Zachary Hartman	UPG	Sep 2001	Dec 2001
Monique Keirlin	UPG	Mar 2002	May 2002
Anne Kiang	UPG	Mar 2003	May 2003
Dana Hancock	UPGG	Aug 2004	Nov 2004
Heather LeBreche	UPGG	Dec 2004	July 2005

Under-Graduate Students

Melissa Moon-Young	Biology	Mar 2000	Dec 2000
Sarah McGill	Biology	Nov 2001	Sep 2001
Todd Mendelson	Biology	Sep 2003	Dec 2004
Brandi L. Thomas	Chemistry	August 2004	Dec 2004

EXHIBIT B

Ph.D. Graduate Students –

-Zachary Hartman (UPGG) March 2002 2006
-awardee, Children Miracles Network Grant : 2005:~$20,000
-Awarded PhD, University Program in Genetics and Genomics: 2006

-Anne Kiang (UPGG) May 2003 2006
-Awardee, 2004 American Society of Gene Therapy Young Investigator Award-Research category.
-Awarded PhD, University Program in Genetics and Genomics:2006.

-Fang Xu (Pathology) Jan 2002 2005

-1st place winner, Pediatrics Dept. Annual Young investigator Research Award, 2003
-Awardee, Childrens Miracle Network Grant: 2004. ~$20,000.
-Awarded PhD, Pathology Dept. DUMC August 2005

Graduate Student Ph.D Committee Member:

-Abigail Brown (UPGG)
-Brian Doehle (MGM)
-Ning Lan (UPGG)
-Monique Kierlin (UPGG)
-Scott Garvey (UPGG)
-Charlie Shaw (UPGG)
-Jennifer Lin (MGM)
-Stephanie Moore (MGM)
-Sabah Oney (UPGG)

Formal Course Lectures

Course Type	Number	Course Title
Medical School	MS-301	IRB Workshop,2004-
Biology-Undergraduate	BIO-280S	Genetic Engineering and Biotechnology-2001-2005
Biology-Undergraduate	BIO-195S	Biotechnology and The new genetics
Pathology-Graduate	PTH -385	Molecular Aspects of Disease,1997- present
Medical Genetics	GEN-200	Gene Therapy Approaches To Human Disease, 1997

EXHIBIT B

Mol Gen. And Microb.-Graduate	MGM-252	Graduate Virology
Mol Gen. And Microb.-Graduate	MGM-232	Human Genetics

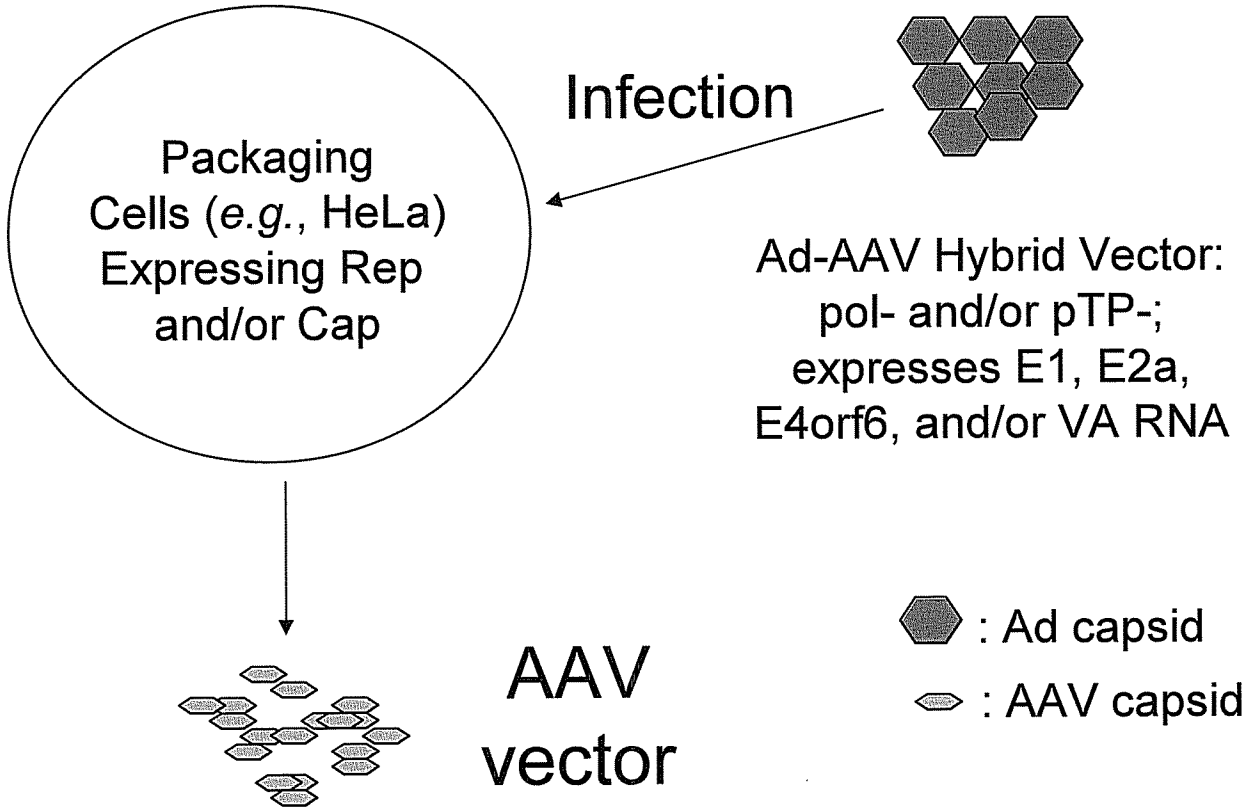
Infection
Packaging
Cells (e.g., HeLa)
Expressing Rep
and/or Cap
Ad-AAV Hybrid Vector:
pol- and/or pTP-;
expresses E1, E2a,
E4orf6, and/or VA RNA
AAV
vector
: Ad capsid
: AAV capsid

Exhibit C

Lieber Method

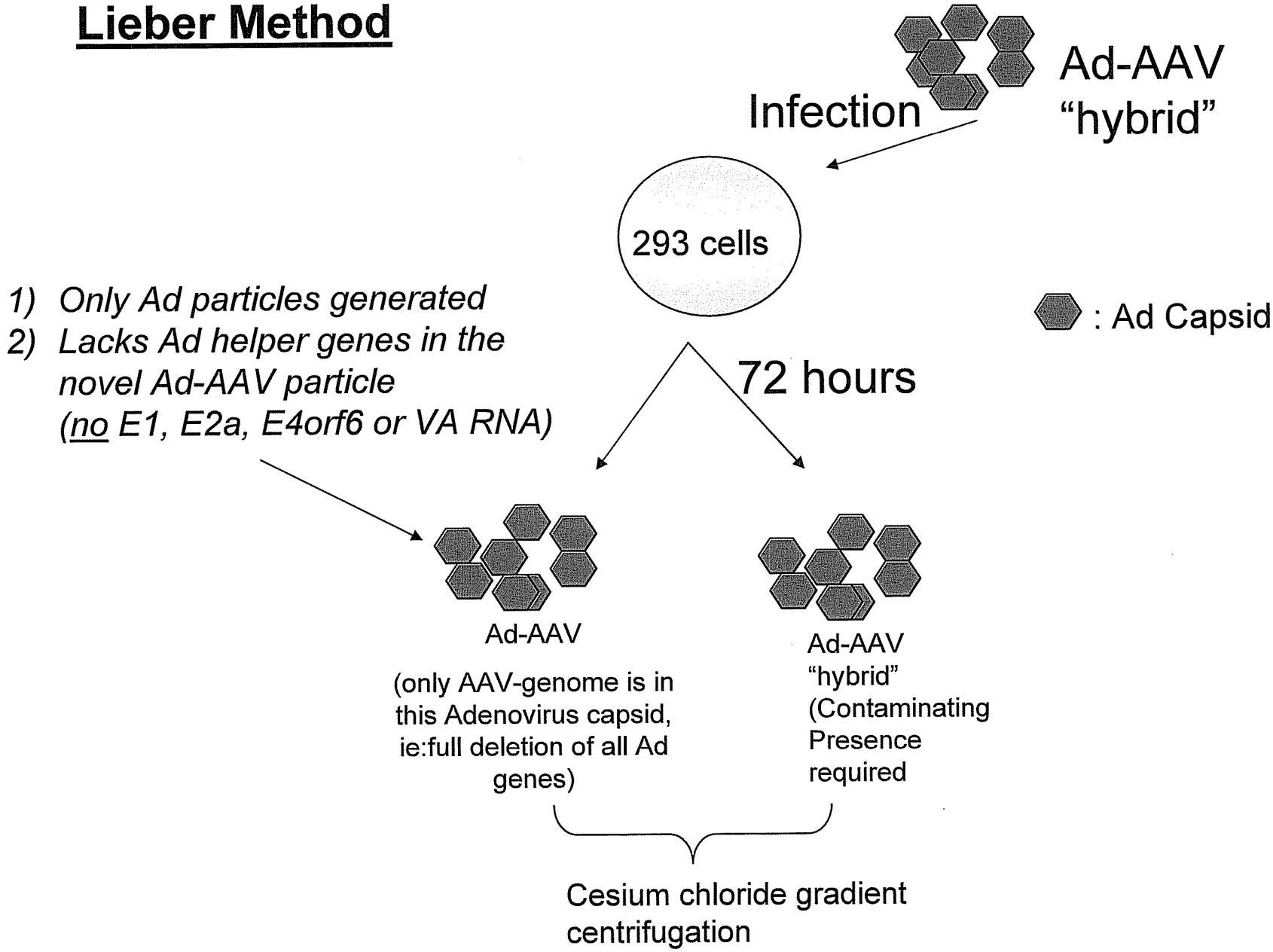

Exhibit D

Mountz Method

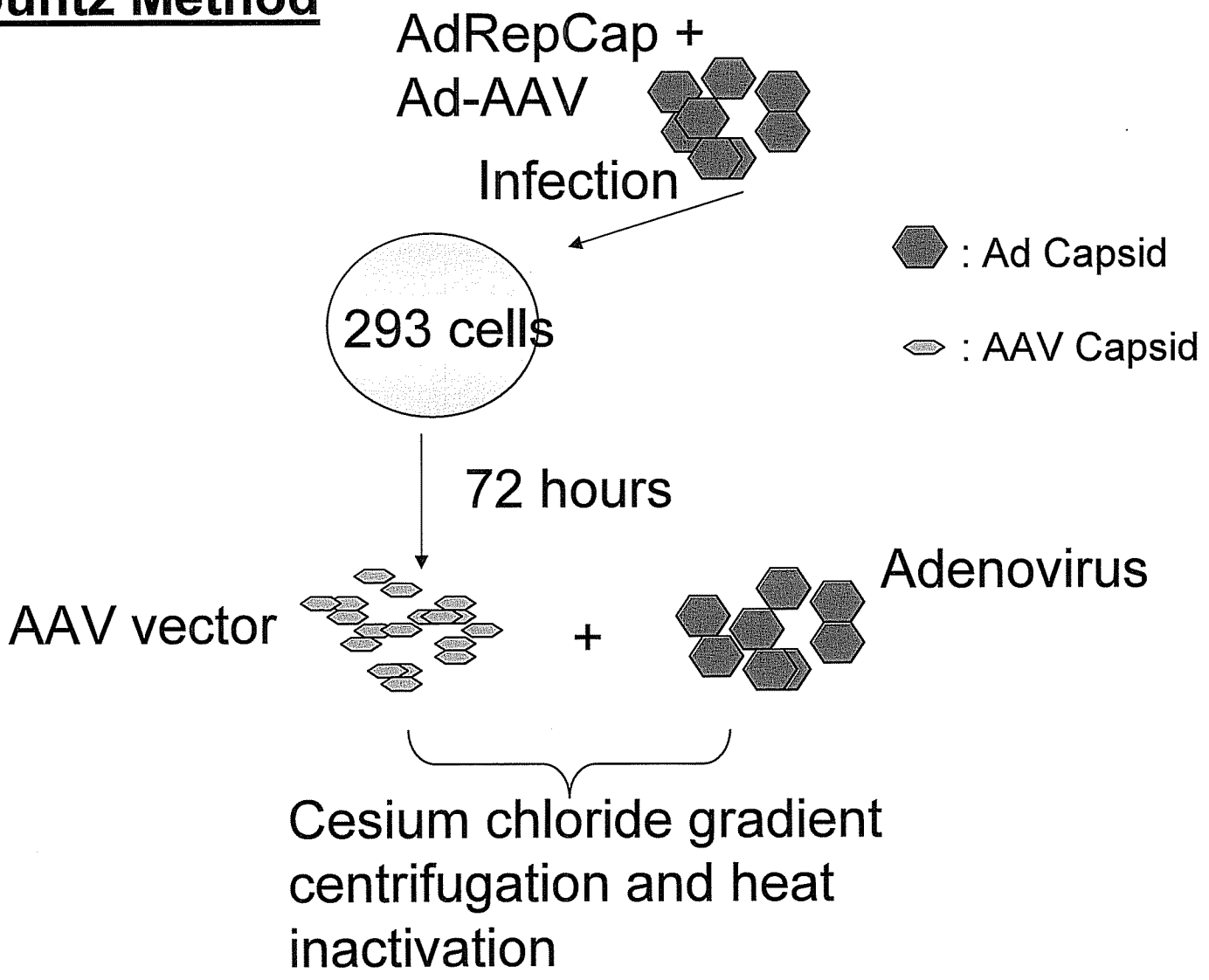

Exhibit E